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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,178	02/01/2001	Tetsuya Ishizuka	P66351US0	7485

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EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/774,178	ISHIZUKA ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/26/2005 has been entered. Claims 1-10, 12-18 and 20-22 have been canceled. Claims 11 and 19 have been amended and are pending in the instant invention.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakahara et al in view of Kievits et al and further in view of Leone et al and Malek et al (*all citations made of record in previous actions*). Regarding claims 11 and 19, Nakahara et al teach a method of amplifying a target RNA comprising the steps of producing double stranded DNA having a T7 promoter sequence by using the target RNA as a template, (b) transcribing the double stranded DNA in a reaction solution in the presence of an RNA polymerase from phage T7 and ribonucleotide triphosphates, wherein the ribonucleotide triphosphates include: adenosine triphosphate (ATP), uridine triphosphate (UTP), cytidine triphosphate (CTP) and guanosine triphosphate (GTP) at a final concentration of 2mM and inosine triphosphate (ITP) at a final concentration of 0 to 4mM to produce transcribed RNA and detecting the product formed therein (see entire reference, especially page 1855, col. 1, Figure 1 legend). Nakahara et al further teach wherein the method is performed in the presence of tris-HCL having a pH 8.5 at a final concentration of 40 mM and magnesium chloride at a final concentration of 12 mM. Nakahara et al differs from the instant invention in that the reference does not teach the repeating the steps using the transcribed RNA. Nakahara et al also does not teach wherein the tris-HCl is present at a final concentration of 50 mM to 80 mM or wherein the transcribing step occurs in the presence of a fluorescently labeled probe.

In a method similar to that of Nakahara et al, Kievits et al teach amplifying a target RNA containing a specific base sequence in a sample by an RNA amplification procedure which comprises a step of forming a double-stranded DNA which has a T7 promoter sequence and is capable of transcribing into an RNA comprising a specific base sequence, a step of forming an RNA transcript comprising the specific base sequence using an RNA polymerase and a step of

forming a double stranded DNA using the RNA transcript as the template, in the presence of adenosine triphosphate (ATP), guanosine triphosphate (GTP), cytosine triphosphate (CTP), uridine triphosphate (UTP) and inosine triphosphate (ITP) as substrates of the RNA polymerase. Kievits et al further teach wherein the transcribed RNA may act as a template for subsequent generation of double stranded DNA template comprising the T7 promoter (col. 3, line 49 to col. 4, line 7, col. 5, line 8 to col. 6, line 29). Kievits et al, like Nakahara et al, do not teach wherein the concentration of tris-HCl is presence at a final concentration of 50 mM to 80 mM. Likewise, Kievits et al do not teach wherein the transcribing step occurs in the presence of a fluorescently labeled probe.

In a method similar to that of Nakahara et al and Kievits et al, Leone et al teach a method of amplifying a target RNA comprising the steps of (a) producing double stranded DNA having a promoter sequence by using the target RNA as a template, (b) transcribing the double stranded DNA in a reaction solution in the presence of an RNA polymerase from phage T7 and ribonucleotide triphosphates, wherein the ribonucleotide triphosphates include: adenosine triphosphate (ATP), uridine triphosphate (UTP), cytidine triphosphate (CTP) and guanosine triphosphate (GTP) at a concentration of 5mM to 10mM and inosine triphosphate (ITP) at a concentration of 2.5 mM to produce transcribed RNA and repeating the steps using the transcribed RNA as the template (page 2151, section entitled "Material and Methods", col. 1 to first paragraph of col. 2). Leone et al further teach wherein the method is performed in the presence of a fluorescently labeled probe that hybridizes with the transcribed RNA and monitoring the fluorescence of the reaction solution, wherein the fluorescently labeled probe alters upon hybridization of the probe with the transcribed RNA (page 2151, col. 1, section

entitled "Materials and Methods" and page 2152-2153, section entitled "Results"). Leone do not teach tris-HCl buffer having a final concentration of 50mM to 80mM. However, Leone et al do teach obtaining stock solutions of Tris-HCl at a concentration of 200mM having a pH 8.5 (page 2151, col. 1, last paragraph) and varying the buffers concentration to optimize RNA detection conditions.

Malek et al provides a general teaching of an RNA amplification method similar to that of Leone for detecting target RNA molecules in the presence of a T7 promoter (page 254). Malek et al provides tips and conditions for preparing and using reagents required in the RNA amplification method. Malek et al teach preparation of stock solutions of rNTPs, NTPs and buffer solutions for use in the RNA amplification reaction. Malek et al teach that a 1M stock solution of Tris-HCL having a pH of 8.5 and 1M stock solution of Magnesium chloride should be prepared or obtained premixed for use in the RNA amplification reaction. Malek et al teach that a 25 mM stock of dNTPs and NTP should be prepared for use in the RNA amplification reaction (see page 254-256). Malek et al teach that these stocks can be diluted to obtain varying concentration to optimize the conditions of the RNA detection (page 257; see also page 258 to 259). Therefore, given the teaching of Malek et al for stock preparation of reagents necessary for the RNA amplification reaction and dilution conditions, one of ordinary skill in the art at the time of the claimed invention would have been motivated to modify or vary the concentrations of reagents required for the RNA amplification reaction of Nakahara et al in view of Kievits et al and Leone et al by e.g., dilution, for the benefit of optimizing the RNA detection conditions as taught by both Leone et al and Malek et al. Additionally, it would have been obvious to one of

ordinary skill in the art at the time of the claimed invention to optimize concentrations of buffers utilized in the assay reaction based on desired results as suggested by Malek et al.

Conclusion

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

CYNTHIA WILDER
PATENT EXAMINER